

#### **§ 1702.4**

by this part, or a satisfactory explanation for the absence of the information. As provided by §1702.4, a petition which is not complete may be closed. To be considered complete, a petition shall include the following:

(1) A statement of the justification for the exemption in accordance with §1702.7,

(2) All reasonably available human experience data, reasonably available relevant experimental data (both human and animal), product and packaging specifications, labeling, and marketing history, in accordance with §§1702.8 through 1702.14,

(b) As used in this regulation, “reasonably available” information is data in the petitioner’s possession; data that has previously been generated by the petitioner, and data that is obtainable from such sources as: Reports from Poison Control Centers; reports of adverse reactions that have been submitted to the petitioner; the medical, pharmacological, and toxicological literature; and information required by the FDA for an Investigational Exemption for a New Drug (IND) or a New Drug Application (NDA).

#### **§ 1702.4 Petitions with insufficient or incomplete information.**

If a petition is submitted that is not complete and does not explain the reason for the absence of the information, the Commission shall afford the petitioner a reasonable opportunity to provide additional information. If the required information is not submitted to the Commission, or if the petitioner does not satisfactorily explain the absence of the information within a reasonable time, the petition shall be closed if insufficient or incomplete information has been submitted to enable the Commission to evaluate the merits of the exemption request.

#### **§ 1702.5 Failure to supply adverse information.**

Failure to obtain and provide the Commission with all reasonably available information that the petitioner knows is unfavorable or could reasonably expect to be unfavorable to the petition shall result in the denial of the petition.

#### **16 CFR Ch. II (1–1–12 Edition)**

#### **§ 1702.6 Trade secrets and other confidential information.**

Where a petition contains material that the petitioner believes should be exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. 552, the petitioner shall comply with the requirements of 16 CFR part 1015, the Commission’s regulation under the Freedom of Information Act concerning requests for treatment as exempt material. The Commission shall act upon any request for treatment as exempt material in accordance with the provisions of 16 CFR part 1015.

#### **§ 1702.7 Justification for the exemption.**

The justification for the exemption, required under §1702.3, shall explain the reason for the exemption based on one or more of the following grounds:

(a) If the justification is based on a lack of need for special packaging to protect young children from serious injury or illness from the substance, the justification shall state how the lack of toxicity and lack of adverse human experience for the substance clearly supports granting the exemption.

(b) If the exemption is requested because special packaging is not technologically feasible, practicable, or appropriate for the substance, the justification shall explain why.

(c) If the exemption is requested because special packaging is incompatible with the particular substance, the justification shall explain why.

#### **§ 1702.8 Human experience data.**

Human experience data constitutes the primary criterion used by the Commission in evaluating petitions for exemptions. Petitions shall therefore include a compilation of all reasonably available reports pertaining to human use of the particular substance, including the product brand as well as generic equivalents and involving adverse reports of personal injury, illness, and significant allergenicity. Such information in children is of particular importance in evaluating exemption requests. However, similar data in adults shall also be submitted if available. Human experience data may be obtained from such sources as: